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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 11 OCT 2004
WIPO PCT

Applicant's or agent's file reference P17929PC00/he	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/NO 03/00208	International filing date *(day/month/year)* 19.06.2003	Priority date *(day/month/year)* 19.06.2002
International Patent Classification (IPC) or national classification and IPC A61M16/00		
Applicant MEDINNOVA SF et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 11 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15.01.2004	07.10.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Krantz, L Telephone No. +49 89 2399-2523

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International application No.
PCT/NO 03/00208

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-10	as originally filed
Claims, Numbers	
1-17	received on 17.09.2004 with letter of 17.09.2004
Drawings, Sheets	
1/11-11/11	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 2-3 , 5-17

because:

☒ the said international application, or the said claims Nos. 15-17 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 2-3, 5-14 are so unclear that no meaningful opinion could be formed *(specify)*:

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1 , 4
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1,4
Industrial applicability (IA)	Yes:	Claims	
	No:	Claims	15-17

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

claims 1 , 4 and 15 are independent .
claim 15 is for a method

The following documents cited in the International Search report have been referred to by means of the following appellation:
D1 : US-A-4 403 215
D2 : US-A-2002-32383
D3 : EP-A-747 005

III

The apparatus of claim 1 was not originally disclosed Article 34.2.b PCT
Some generalisations and omissions have been made in claim 1 which were not originally suggested.
In original claim 1 there was a CONNECTION UNIT.
Original claim 3 specified this CONNECTION UNIT to include a PROCESSING UNIT which according to original claim 3 and also according to fig 4 (processing unit 10) and page 8 fourth line always includes a memory unit.
This memory unit now suddenly has been left out in claim 1 which is an impermissible generalisation , cf. claim 7.
A PROCESSING UNIT without a memory unit was not originally suggested.

In original claim 1 the electrodes were specially adapted for placement on the THORACIC cavity not on- or in other places in the human body and the processing unit in original claim 3 was adapted to treat thoracic impedance because "analysing impedance signals" in original claim 3 referred to the impedance in original claim 1 which was exclusively thoracic impedance.
Also the impedances top of page 8 in the processing unit 10 are thoracic impedance see page 7 line 40 "measurement of thoracic impedance"
This special design of- or special software inside the processing unit 10 has now been left out in claim 1 where the electrodes merely measure SOME impedance of the human body.

It was not originally suggested or shown how it is possible to determine

correct ventilation by measuring impedance on OTHER positions than the thoracic cavity , for instance impedance in the feet.

III .2

The apparatus of claim 4 was not originally disclosed
claim 4 repeats all hardware-units of claim 1 whereby the above also goes for claim 4.
It is furthermore confusing in claim 4 that a memory is not defined until in claim 7.
The apparatus in claim 4 is said to be PROGRAMMABLE this is not possible without a memory.

III .3

The claims are not concise Article 6 PCT
In independent claim 4 all hardware-components of claim 1 are repeated:
- processing unit
- measuring unit with two electrodes
- power source
- display device

Since all hardware items in claim 1 are electronic
(no mechanical unit exists which can determine impedance)
then the reader of claim 1 may well conclude that the processing unit in claim 1 contains a microprocessor , uP , and can be programmed since uP-controlled measuring devices are very common.
claim 4 merely adds to the components of claim 1 that the processing unit can be programmed which is no surprise to the reader of claim 1 , whereby claim 4 should have been formulated as dependent on claim 1.

III .4

The category (method / device) of claims 1 and 2 is unclear
PCT-Guidelines C-III 3.1
claim 1 reads "in use ... the processing unit identifying a ... change"
these are steps in a method and should have been formulated:
"in use ... the processing unit MAY IDENTIFY a ... change"
The same problem is in claim 2 :
"in use a correct placement ... is indicated ... identifying a ... change"
This diffuse formulation of claim 1 has great importance for
comparison with prior art D1
Thus the electronic device in D1 is not suggested to "in use" survey
the position of an endo-tracheal tube but is FULLY CAPABLE to
do it , see below.

III .5

claims 15 - 17 are not examined due to Rule 67.1.iv PCT
(therapy and diagnostic method)
If a medical doctor takes action to improve the bodily situation of a patient then
this is a therapy and any use of an apparatus which use helps the doctor
to take this action or maybe even initiates the doctor to take this action
by sending out some alarm is a step in this therapy.
If this apparatus (eg. a thermometer) also helps the doctor to take decisions
then use of the apparatus is also part of a diagnostic method.
In the method in claim 15 impedance signals from the thorax are measured.
If the changes in impedance are absent or small this may well be
an indication of absence of inflation of the lungs (see also fig 3B)
ie. wrong position of an endo-tracheal tube and then an alarm is given
see claim 15:
"and activating a second ... alarm ... to indicate incorrect intubation"
Therefore the measurement in claim 15 is the first step in a procedure
where the doctor or a nurse takes an action to improve the bodily situation
of a patient , namely repositions the endo-tracheal tube.

Without the measurement-method the patient will get no therapy and
may die se page 1 line 17:
"... or even death may result"

whereby it is seen that the measurement is the first step in a life-saving therapy.

This is in accordance with Applicants letter of 17 Sep. 2004 page 4 top:
"The results of this analysis are then used to indicate incorrect intubation"
If such claims were patented then medical personnel would have to
pay licenses every time they hear the alarm.

V

The subject-matter of claim 1 is not new over D1

Due to the above ambiguities and problems in the claims
merely a limited opinion is given about the prior art.

An endo-tracheal tube is NOT part of claim 1.
If such a tube is erroneously placed in the esophageus
(invention page 1 line 15)
then the depth of respiration of the patient changes and becomes
very small or disappears and this is exactly what the device in D1
measures see D1 column 3 line 29:
"The output signal voltage ΔV of amplifier 16 is proportional to
THE DEPTH OF RESPIRATION of the patient "
Amplifier 16 is not shown in detail in fig 1 of D1 but it is clear from
the position of signal ΔV that amplifier 16 is at the output of
current source 10.
This voltage ΔV in D1 fig 1 naturally is directly proportional to
the chest-impedance see D1 column 3 line 25 :
"The changes in the impedance of the body between the electrodes
is monitored by ... amplifier 16 ... The output signal voltage ΔV of
amplifier 16 is proportional to the depth of respiration".
Thus voltage ΔV is a direct measure of chest-impedance during respiration.

It does not matter for whatever reason , change in this chest-impedance becomes
too small , the device in D1 will give an alarm 26 in any case , also
if for instance an endo-tracheal tube has been dislocated.
In D1 fig 1 the average value of a series of chest-impedances by respiration

is found by peak-detector 28 + integrator 36 and the doctor may modify this average by multiplicator 42.
This average VT is compared with the actual impedance by comparator 22 D1 fig 1 and if the actual impedance becomes too small then an alarm 26 is given D1 column 4 line 19
"as long as inspirations of sufficient magnitude continue to occur ..."

Thus all hardware features of claim 1 of the invention are seen in D1 fig 1:
- processing unit 22 , 28 , 36 , 42
  for identifying 22 impedance amplitude changes ΔV

- measuring unit 10 with two measuring-electrodes 12

- power source (the supply for all circuits in D1)

- alarm 26

- the processing unit 22 , 28 , 36 , 42 identifies VT
  a significant change 22 in the impedance amplitude ΔV

Thus the present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claim 1 is not new , Rule 64 PCT.

It may be argued that :
"...all of the cited prior art documents are directed towards the detection of only very small changes in the volume of the lungs due to normal breathing"

This is not agreed upon. As seen from the above ,

the output signal voltage ΔV of amplifier 16 is proportional to the depth of respiration , whereby if the change in the volume of the lungs is big then the output signal will also have a big amplitude and will even be easier to detect than a small output

(small signals are always more difficult to detect than larger due to the signal-to-noise ratio , S / N)

V .2

The subject-matter of claim 4 is not new over D2

- processing unit 64 D2 fig 3
  for respiration impedance changes D2 fig 5

- measuring unit 52 fig 3

- two electrodes 12 , 14

- power source 20

- alarm or display 70

- processing unit CPU-64 is programmed to identify
  significant impedance changes
  D2 fig 5 0.6 ohms , cf. that the threshold used in claim 3
  of the invention is in the same range 0.5 ohm
  Naturally larger changes will be even easier to detect
  due to a large S / N ratio
  D2 page 3 : "use of software with a computer to detect
  impedance changes ... of a patient "

If in claim 4 MORE than two measuring electrodes were used then D3 becomes relevant :

More than one chest electrode (claim 2) is used in D3 to avoid that the impedance of the electrodes themselves is included in the total impedance see D3 column 3 line 20
"...eliminates the earlier problems resulting from ... cable impedances being summed with the impedance to be measured"

VII

Other problems
The drawings do not meet the requirements of PCT-Rule 11.13
The lines are ill and shakingly drawn by hand 11.13.f
and are not uniformly thick and well-defined 11.13.a
The numbers and letters in the figures are partly illegible handwriting 11.13.e
Figures 10 and 11 are dim and blurred photos of oscilloscope-screens
and are totally unsuited for reproduction 11.13.c
In figure 7 "power supply krets" should be "power supply circuit"

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 , D2 and D3 is not mentioned in the description, nor are these documents identified therein.

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